APR 2 9 2004

EXHIBIT # 14

510(k) Summary K033453

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Kendall, a Division of Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: October 23, 2003

1. Contact Person

Gail Christie
Manager, Regulatory Affairs
(508) 261-8440

2. Name of Medical Device

Classification Name: Hydrocolloid Dressing
Proprietary Name: ULTEC PRO Ag+ Hydrocolloid Dressing

3. Identification of Legally Marketed Device

The proposed device, Kendall ULTEC PRO Ag+ Hydrocolloid Dressing is substantially equivalent in intended use, function and composition to the Kendall ULTEC PRO Hydrocolloid Dressing (K943636), Arglaes Antimicrobial Film Dressing (K990810), and Contreet Hydrocolloid Dressing with silver (K013525).

4. Device Description

The proposed Kendall ULTEC PRO Ag+ Hydrocolloid Dressing is a sterile, single use, highly flexible wound dressing designed for use on dry to lightly exudating wounds. ULTEC PRO Ag+ Hydrocolloid Dressing was designed to create and maintain a moist wound environment that is optimal for wound healing.

The alginate formulation of ULTEC PRO Ag+ releases anti-microbial silver and absorbs wound exudates. The release of anti-microbial silver enhances the barrier properties of the hydrocolloid by reducing bacterial growth on the dressing.

The proposed wound dressing consists of 65 % acrylic hot melt pressure sensitive adhesive, 25 % sodium alginate, and 10 % inorganic polymer containing silver.

5. Device Intended Use

ULTEC PRO Ag+ Hydrocolloid Dressings are intended for use on venous stasis ulcers, pressure ulcers, arterial ulcers, diabetic ulcers, donor sites, lacerations, post surgical incisions, and other external wounds presenting dry to lightly exuding symptoms.

6. Product Comparison

The proposed device has the same technological characteristics as the predicate devices. Both the proposed device and the Contreet Hydrocolloid Dressing with silver consist of a hydrocolloid base with added silver.

Both the proposed ULTEC PRO Ag+ Hydrocolloid Dressing and the Arglaes Dressing utilize a silver based antimicrobial agent that is formulated from ionic silver encapsulated in a water soluble polymer structure. The silver polymer matrix used in the Arglaes product contains the same elemental components as those used in the proposed device. The silver polymer used in these devices is obtained from the same manufacturer.

Both the predicate device, UTEC PRO Hydrocolloid Dressing and the proposed ULTEC PRO Ag+ Hydrocolloid Dressing contain adhesive and alginate.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Ms. Gail Christie
Manager, Scientific Services/Regulatory Affairs
Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K033453
Trade/Device Name: Kendall Ultec Pro Ag+ Hydrocolloid Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 10, 2004
Received: February 13, 2004

Dear Ms. Christie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K033453

Device Name: Kendall Ultec Pro Ag+ Hydrocolloid Dressing

Indications for Use:

The Ultec Pro Ag+ Hydrocolloid Dressings are indicated for use on venous stasis ulcers, pressure ulcers, arterial ulcers, diabetic ulcers, donor sites, lacerations, post surgical incisions, and other dry to lightly exudating symptoms.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033453